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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/906,713	08/05/97	LOK S	97-52

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EXAMINER	
KAUFMAN, C	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 09/14/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/906,713	Applicant(s) Lok et al.
	Examiner Claire M. Kaufman	Group Art Unit 1646

☒ Responsive to communication(s) filed on *Jun 9, 1998* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *20-23 and 27-29* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *20-23 and 27-29* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The amendment filed June 9, 1998 has been entered.

Election/Restriction

2. Applicant's election without traverse of Group II in Paper No. 7 is acknowledged.

Abstract

3. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation; (2) if an article, its method of making; (3) if a chemical compound, its identity and use; (4) if a mixture, its ingredients; (5) if a process, the steps.

In the current instance, the abstract does not list the identity of the compound: Zcytor11, a class II cytokine receptor.

Specification

4. The disclosure is objected to because of the following informality: on page 13, line 2, it appears that "blossom 62" should be --"BLOSUM 62"--.

Appropriate correction is required.

Claim Objections

5. Claim 27 is objected to because of the following informality: Claim 27 is missing a comma in line 3 after "574".

6. Claims 28, 29 and 22 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Since parent claim 20 recites a single species and dependent claims 28 and 29 are apparently broader than the parent, they do not further limit it. (See section 9 below for indefiniteness of claim 20.)

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 21 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide comprising amino acid residues 18-228 of SEQ ID NO:2 and a transmembrane domain and an intracellular domain from a second receptor or from the receptor having the sequence of SEQ ID NO:2, does not reasonably provide enablement for the use of an intracellular domain not able to transduce a signal, *i.e.*, not from a receptor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claim is drawn to a polypeptide which has amino acids 18-228 of SEQ ID NO:2 and further has a transmembrane domain or an intracellular domain or both. (See section 9 below for indefiniteness of independent claim 20.) The specification teaches that the extracellular domain of

Zcytor11 is amino acids 18-228 of SEQ ID NO:2 and that is where ligand binding occurs (p. 25, lines 32-33). Also taught is production of a hybrid receptor that has the extracellular domain of Zcytor11, a transmembrane domain, and the intracellular domain from a different receptor, for detection of a Zcytor11 ligand (paragraph bridging pages 25-26). A soluble receptor is described, but comprises neither an intracellular nor a transmembrane domain (paragraph bridging pages 7-8). The claim is not limited to a particular transmembrane domain or, more importantly, a particular type of intracellular domain. Proteins which are not receptors, but which are expressed on the cell surface typically have an intracellular domain, however, that domain does not necessary transduce a signal. The specification has not taught how to use a hybrid polypeptide having an extracellular domain and intracellular domain without a transmembrane domain or having an extracellular domain, a transmembrane domain, and a non-receptor intracellular domain. In these two cases, no signal would be produced by ligand binding and there is no guidance on how to use a hybrid polypeptide having the Zcytor11 extracellular domain and a transmembrane and/or intracellular domain which does not transduce a signal upon ligand binding. For these reasons, it would require undue experimentation to use the claimed invention.

8. Claims 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide comprising a fragment of SEQ ID NO:2 from amino acid residue 1-251, 1-228, 18-228, 18-251, 18-574, 229-251, or 252-574, or the full sequence of SEQ ID NO:2, does not reasonably provide enablement for a polypeptide comprising a sequence which is at least 90% or 95% identical to residues 18-228 of SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The current claims are drawn to a polypeptide which is at least 90% identical to amino acids 18-228 of SEQ ID NO:2. The polypeptide having the sequence of SEQ ID NO:2 has been identified as Zcytor11, a class II cytokine receptor, however the ligand for the receptor is

unknown. The specification discloses that the ligand binding domain (amino acids 18-228 of SEQ ID NO:2) of the receptor can be used as part of a hybrid receptor for ligand identification (paragraph bridging pages 25-26). Additionally, the polypeptide may be used to generate antibodies which bind Zcytor11 (p. 30, line 10, through, p. 31, line 16), for purposes of tagging cells expressing the receptor or for determining levels of circulating receptor. Which amino acids within the extracellular domain are necessary for ligand binding are not disclosed. The claimed polypeptide is not required to be naturally occurring. The specification does not provide guidance to determine which amino acids could be changed while retaining ligand binding activity. Since the ligand of the receptor is not known, there is no way to test whether activity is retained. In order to produce an antibody that binds Zcytor11, the antibody must bind an epitope of the antigen. If the antigen is in native conformation, the three-dimensional positioning of the epitope is important. If it is in a denatured form, the two dimensional structure is important (see Stites et al., V, p. 53). This means that not only the amino acids being bound by the antibody are important, but the amino acids around those bound are important for proper conformation. Changing amino acids in an epitope or which are responsible for conformation would reasonably be expected to eliminate antibody binding. This is true of polypeptides which share less than 100% identity. The specification does not teach how to use a polypeptide which neither binds a ligand nor an antibody to Zcytor11. For these reasons, it would require undue experimentation to use the claimed polypeptide.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 20-23, 28, 29 and dependent claim 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is indefinite because it is unclear if the meaning of a polypeptide "comprised of" an amino acid sequence is that i) the polypeptide contains amino acids 18-228 of SEQ ID NO:2 and nothing else, or ii) the polypeptide comprises amino acids 18-228 of SEQ ID NO:2 and may comprise other amino acids, labels, *etc.*

Claims 21 and 23 are unclear to because the claims recite "further containing"; however, "containing" is closed language, and it is confusing to say something further contains something else when containing implies a single thing. This rejection could be obviated by saying "further comprising", which is open language.

Claim 22 recites the limitation of residues 229-574 of SEQ ID NO:2. There is insufficient antecedent basis for this limitation in the claim. Because parent claim 20 can be interpreted as limited to amino acids 18-228 of SEQ ID NO:2, residues outside of 18-228 do not have sufficient antecedent basis. In order for sufficient antecedent basis in claim 20, the parent claim would need to recite amino acids 229-574 of SEQ ID NO:2.

Claims 28 and 29 are indefinite because of the recitation of % identical. There is no one art recognized way to calculate identity. The value obtained for two sequences depends not only one which sequence is chosen as the reference sequence, but also if gaps are allowed, and what the gap weight and best fit parameters are chosen to be. The particular algorithm used will also determine the value obtained. In the current specification, two examples of methods that may be used are disclosed and gap opening and extension penalties are specified. However, examples are non-limiting. In term so of the penalties, although the claims are interpreted in light of the specification, limitation from the specification are not read into the claims. This rejection could be obviated by specifying in the claims how identity is calculated, *e.g.*: --wherein identity is calculated as

Total number of identical matches
--X 100

[length of the longer sequence plus the number of gaps introduced into the longer sequence in order to align the two sequences]

with a gap opening penalty of 10, a gap extension penalty of 1, and the BLOSUM 62 scoring matrix.--

Prior Art

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Henikoff et al. (U) teach a method of aligning proteins sequences, which method is relied upon for the example present on page 13 of the current specification for calculating % identity. Moore et al. (A) disclose a mammalian interleukin-10 receptor, which is a class II cytokine receptor and, therefore, related to the currently claimed receptor. The prior art does not teach the claimed polypeptide.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Friday from 8:00AM to 4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached at (703) 308-2731.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

cmk
September 9, 1998

LILA FEISEE
SUPERVISORY PATENT EXAMINER
GROUP ~~1800~~ 1600